UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/996,631	11/28/2001	Kenneth W. Dick	LIFE031	4048

7590 10/03/2003

Frank P. Becking
Bozicevic, Field and Francis LLP
Suite 200
200 Middlefield Road
Menlo Park, CA 94025

EXAMINER	
NOGUEROLA, ALEXANDER STEPHAN	

ART UNIT	PAPER NUMBER
1753	

DATE MAILED: 10/03/2003

3

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/996,631	DICK ET AL.	
	Examiner	Art Unit	
	ALEX NOGUEROLA	1753	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 3-21* is/are rejected.

7)☒ Claim(s) *2* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *28 November 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *2* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

Claim Objections

1. Claims 1, 2, and 15 are objected to because of the following informality:

a) Claim 1, line 2: insert -- a – between "coating" and "substrate";

a) Claim 2, line 2: -- said -- should be inserted between "to" and "radiant"; and

c) Claim 15, line 3: insert -- a -- between "comprising" and "substrate".

Appropriate correction is required.

Claim Rejections - 35 USC § 112

2. Claims 3, 6, and 8-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention:

a) Claim 3, line 2: -- radiant -- should be inserted between "said" and "energy";

b) Claim 6 recites the limitation "said feeding" in line 1. There is insufficient antecedent basis for this limitation in the claim. Note that claim 3, from which claim 6 appears to properly depend, recites "is fed";

c) Claim 8 recites the limitation "dried reagent" in line 1. There is insufficient antecedent basis for this limitation in the claim;

Note that dependent claims will have the deficiencies of base and intervening claims.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1, 4, 5, 8, 9-13, and 18 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Shieh et al. (US 5,401,377).

Addressing Claim 1, The Shieh et al. reference teaches a method of producing a reagent-coated substrate comprising

coating substrate with reagent in solution (claim 16, step (c) and col. 11, ln. 45 – col. 12, ln. 22), and

exposing the solution to radiant energy provided by at least one radiant energy heater (col. 12, ll. 23-39, especially col. 12, ll. 30-37).

Addressing Claim 4, a cross-section of one stripe is shown in Figure 1A.

Addressing Claim 5, although not stated the substrate inherently will be reflective to some extent as no perfect black body is known.

Addressing Claim 8, Figures 1 and 1A show a substantially uniform thickness of dried reagent.

Addressing Claim 9, an inert backing layer (12,29) and a metallic coating (14, 24) are shown in Figures 1 and 1A.

Addressing Claims 10-12, the coated substrate in the Shieh et al. reference is in a test strip, more precisely a reagent test strip, and still more precisely an electrochemical-type test strip (the abstract and Figure 2).

Addressing Claim 13, a pair of electrodes and a spacer as claimed are disclosed in Figure 1A and col. 4, ln. 55 – col. 5, ln. 13.

Addressing Claim 18, Applicant's detecting and relating steps are taught by Example 1 (col. 14, ll. 7-57) and Example 5 (col. 16, ll. 20-48), which teach making hydrogen ion and sodium ion concentration measurements, respectively.

5. Claims 1, 5, and 10-12 are rejected under 35 U.S.C. 102(b) as being anticipated by van der Wal et al. (US 5,238,548).

Addressing Claim 1, the van der Wal et al. reference teaches a method of producing a reagent-coated substrate comprising

coating substrate with reagent in solution (col. 4, ll. 50-59), and

exposing the solution to radiant energy provided by a t least one radiant energy heater (col. 4, ll. 50-59, especially col. 4, ll. 41-43).

Addressing Claim 5, although not stated the substrate inherently will be reflective to some extent, as no perfect black body is known.

Addressing Claims 10-12, the coated substrate in the van der Wal reference is in a test strip, more precisely a reagent test strip, and still more precisely an electrochemical-type test strip (the abstract and Figure 1A).

6. Claims 1, 4, 5, 8, 9-12, and 18 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Hanazato et al. (US 4,894,339).

Addressing claim 1, the Hanazato et al. reference teaches a method of producing a reagent-coated substrate comprising

coating substrate with reagent in solution (col. 2, ll. 37), and

exposing the solution to radiant energy provided by at least one radiant energy heater (col. 2, ll. 37-47).

Addressing Claim 4, a top view of one stripe is shown in Figure 4.

Addressing Claim 5, although not stated the substrate inherently will be reflective to some extent, as no perfect black body is known.

Addressing Claim 8, Figures 3C and 5 show a substantially uniform thickness of dried reagent.

Addressing Claim 9, an inert backing layer (1111) and a metallic coating (113, 114) are shown in Figure 4.

Addressing Claims 10-12, the coated substrate in the Hanazato reference is in a test strip, more precisely a reagent test strip, and still more precisely an electrochemical-type test strip (the abstract and Figure 11).

Addressing Claim 18, Applicant's detecting and relating steps is taught by Example 12 (col. 14, ll. 25-36) which teaches making glucose ion concentration measurements.

Claim Rejections - 35 USC § 103

7. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 7 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shieh et al. (US 5,401,377).

Addressing Claim 7, the Shieh et al. reference teaches a method of producing a reagent-coated substrate comprising

coating substrate with reagent in solution (claim 16, step (c) and col. 11, ln. 45 – col. 12, ln. 22), and

exposing the solution to radiant energy provided by at least one radiant energy heater (col. 12, ll. 23-39, especially col. 12, ll. 30-37).

The Shieh et al. reference does not mention the intensity of the radiant energy; however, barring evidence to the contrary, such as unexpected results, choosing the intensity of the radiant energy, such as an intensity within the claimed range, is just a matter of optimizing the coating method. The intensity of the radiant energy used will be primarily limited by possible damage to

the coating or substrate. For example, an excessive intensity of radiant energy can damage the reagent, such as an enzyme, directly or indirectly, by excessive heating.

Addressing claim 19, the Shieh et al. reference teaches a method for determining the concentration of an analyte in a sample, the method comprising providing a reagent-coated substrate prepared (as required by claim 8) by

coating substrate with reagent in solution (claim 16, step (c) and col. 11, ln. 45 – col. 12, ln. 22), and

exposing the solution to radiant energy provided by at least one radiant energy heater (col. 12, ll. 23-39, especially col. 12, ll. 30-37).

Note that Figures 1 and 1A show a substantially uniform thickness of dried reagent.

Applicant's detecting and relating steps are taught by Example 1 (col. 14, ll. 7-57) and Example 5 (col. 16, ll. 20-48), which teach making hydrogen ion and sodium ion concentration measurements, respectively.

Although not specifically mentioned, it would have been obvious to one with ordinary skill in the art at the time the invention was made to make measurements on a biological sample because the Shieh et al. reference teaches that it can be so used (col. 5, ll. 10-13).

10. Claims 14-16 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shieh et al. (US 5,401,377) in view of Nankai et al. (US 5,266,179) and North et al. (US 5,221,457).

Addressing claim 14, the Shieh et al. reference teaches a method of producing a reagent-coated substrate comprising

coating substrate with reagent in solution (claim 16, step (c) and col. 11, ln. 45 – col. 12, ln. 22), and

exposing the solution to radiant energy provided by at least one radiant energy heater (col. 12, ll. 23-39, especially col. 12, ll. 30-37).

Note that Figures 1 and 1A show a substantially uniform thickness of dried reagent.

The Shieh et al. reference does not mention whether the reagent test strip can be read by a hand meter; however, adapting a reagent test strip so that it can be read by a hand meter was known at the time of the invention as shown by the abstract and Figure 3 of the Nankai et al. reference and the abstract and Figure 1 of the North et al. reference. It would have been obvious to one with ordinary skill in the art at the time the invention was made to adapt the reagent test strip so that it can read by a hand meter as taught by the Nankai et al. reference and the North et al. reference because the Shieh et al. reference teaches that the reagent test strip is miniature and may comprise part of a kit for analyzing biological fluids and for titrations (col. 5, ll. 10-13) and if the reagent test strip can be read by a hand meter it will be more convenient to use and on-site results of the measuremetns can be readily obtained.

Addressing claim 15, the Shieh et al. reference teaches a system for determining the concentration of an analyte in a physiological sample comprising a reagent test strip prepared (as required by claim 8) by

coating substrate with reagent in solution (claim 16, step (c) and col. 11, ln. 45 – col. 12, ln. 22), and

exposing the solution to radiant energy provided by at least one radiant energy heater (col. 12, ll. 23-39, especially col. 12, ll. 30-37).

Note that Figures 1 and 1A show a substantially uniform thickness of dried reagent.

The Shieh et al. reference does not mention a hand meter that can interface with the reagent test strip; however, adapting a reagent test strip so interface with and be read by a hand meter was known at the time of the invention as shown by the abstract and Figure 3 of the Nankai et al. reference and the abstract and Figure 1 of the North et al. reference. It would have been obvious to one with ordinary skill in the art at the time the invention was made to adapt the reagent test strip so that it can read by a hand meter as taught by the Nankai et al. reference and the North et al. reference because the Shieh et al. reference teaches that the reagent test strip is miniature and may comprise part of a kit for analyzing biological fluids and for titrations (col. 5, ll. 10-13) and if the reagent test strip can be read by a hand meter it will be more convenient to use and on-site results of the measurements can be readily obtained.

Addressing claim 16, the reagent test strip being received by the meter is shown in Figure 2 of the Nankai et al. reference and implied by col. 2, ll. 39-42, which teaches that the sensor can be inserted into the meter.

Addressing claim 21, the Shieh et al. reference teaches a method for determining the concentration of an analyte in a sample, the method comprising providing a reagent-coated substrate prepared (as required by claim 8) by

coating substrate with reagent in solution (claim 16, step (c) and col. 11, ln. 45 – col. 12, ln. 22), and

exposing the solution to radiant energy provided by at least one radiant energy heater (col. 12, ll. 23-39, especially col. 12, ll. 30-37).

Note that Figures 1 and 1A show a substantially uniform thickness of dried reagent.

Applicant's detecting and relating steps are taught by Example 1 (col. 14, ll. 7-57) and Example 5 (col. 16, ll. 20-48), which teach making hydrogen ion and sodium ion concentration measurements, respectively.

The Shieh et al. reference does not mention a hand meter that can interface with the reagent test strip; however, adapting a reagent test strip so interface with and be read by a hand meter was known at the time of the invention as shown by the abstract and Figure 3 of the Nankai et al. reference and the abstract and Figure 1 of the North et al. reference. It would have been obvious to one with ordinary skill in the art at the time the invention was made to adapt the reagent test strip so that it can read by a hand meter as taught by the Nankai et al. reference and the North et al. reference because the Shieh et al. reference teaches that the reagent test strip is miniature and may comprise part of a kit for analyzing biological fluids and for titrations (col. 5, ll. 10-13) and if the reagent test strip can be read by a hand meter it will be more convenient to use and on-site results of the measurements can be readily obtained.

11. Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Shieh et al. (US 5,401,377) in view of Leader et al. (US 5,421,981) and Savage et al. (US 5,284,570).

Addressing claim 17, the Shieh et al. reference teaches a kit (col. 5, ll. 10-13) comprising

a reagent-coated substrate for use in determining the concentration of an analyte in a physiological sample, comprising

a reagent test strip prepared (as required by claim 8) by

coating substrate with reagent in solution (claim 16, step (c) and col. 11, ln. 45 – col. 12, ln. 22), and

exposing the solution to radiant energy provided by at least one radiant energy heater (col. 12, ll. 23-39, especially col. 12, ll. 30-37).

Note that Figures 1 and 1A show a substantially uniform thickness of dried reagent.

The Shieh et al. reference does not mention providing a reagent test strip in a kit that also includes directions for use, a means for obtaining a physiological sample and an analyte standard.

The Leader et al. reference and the Savage et al. reference teach providing in a kit for a reagent test strip means for obtaining a physiological sample and an analyte standard (in the Leader et al. reference seethe abstract; Figure 1; col. 14, ll. 1-4; and col. 14, ll. 34-41. in the Savage et al. reference see the abstract and Figure 4). It would have been obvious to one with ordinary skill in the art at the time the invention was made to include in a kit for a reagent test strip means for obtaining a physiological sample and an analyte standard as taught by the Leader et al. reference and the Savage et al. reference in the Shieh et al. reference because it is more convenient for the person who will use the reagent test strip to have the necessary components

altogether in a kit so that the reagent test strip can be more quickly set up for use than if these components were separately stored.

As for directions for use, it would have been obvious to provide such directions so that the reagent test strip will be properly used.

12. Claims 7, 8, and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over van der Wal et al. (US 5,238,548).

Addressing Claim 7, the van der Wal et al. reference teaches a method of producing a reagent-coated substrate comprising

coating substrate with reagent in solution (col. 4, ll. 50-59), and

exposing the solution to radiant energy provided by at least one radiant energy heater (col. 4, ll. 50-59, especially col. 4, ll. 41-43).

The van der Waal et al. reference does not mention the intensity of the radiant energy; however, barring evidence to the contrary, such as unexpected results, choosing the intensity of the radiant energy, such as an intensity within the claimed range, is just a matter of optimizing the coating method. The intensity of the radiant energy used will be primarily limited by possible damage to the coating or substrate. For example, an excessive intensity of radiant energy can damage the reagent, such as an enzyme, directly or indirectly, by excessive heating.

Addressing Claim 8, the van der Wal et al. reference teaches a method of producing a reagent-coated substrate comprising

coating substrate with reagent in solution (col. 4, ll. 50-59), and

exposing the solution to radiant energy provided by at least one radiant energy heater (col. 4, ll. 50-59, especially col. 4, ll. 41-43).

The van der Waal et al. reference does not mention a substantially uniform dried reagent thickness; however, it would have been obvious to one with ordinary skill in the art at the time the invention was made to make the dried reagent layer uniform because this will increase the likelihood of uniform exposure of sample to reagent.

Addressing Claim 18, Applicant's detecting and relating steps are taught by Examples 1-3 (col. 4, ln. 33 – col. 5, ln. 11) which teaches making calcium ion concentration measurements.

13. Claims 14-16 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over van der Wal et al. (US 5,238,548) in view of Nankai et al. (US 5,266,179) and North et al. (US 5,221,457).

Addressing claim 14, the van der Wal et al. reference teaches a method of producing a reagent-coated substrate comprising

coating substrate with reagent in solution (col. 4, ll. 50-59), and

exposing the solution to radiant energy provided by at least one radiant energy heater (col. 4, ll. 50-59, especially col. 4, ll. 41-43).

The van der Waal et al. reference does not mention a substantially uniform dried reagent thickness; however, it would have been obvious to one with ordinary skill in the art at the time

the invention was made to make the dried reagent layer uniform because this will increase the likelihood of uniform exposure of sample to reagent.

The van der Waal et al. reference also does not mention whether the reagent test strip can be read by a hand meter; however, adapting a reagent test strip so that it can be read by a hand meter was known at the time of the invention as shown by the abstract and Figure 3 of the Nankai et al. reference and the abstract and Figure 1 of the North et al. reference. It would have been obvious to one with ordinary skill in the art at the time the invention was made to adapt the reagent test strip so that it can read by a hand meter as taught by the Nankai et al. reference and the North et al. reference because if the reagent test strip can be read by a hand meter it will be more convenient to use and on-site results of the measurements can be readily obtained.

Addressing claim 15, the van der Waal et al. reference teaches a system for determining the concentration of an analyte in a physiological sample comprising a reagent test strip prepared (as required by claim 8) by

coating substrate with reagent in solution (col. 4, ll. 50-59), and

exposing the solution to radiant energy provided by at least one radiant energy heater (col. 4, ll. 50-59, especially col. 4, ll. 41-43).

The van der Waal et al. reference does not mention a substantially uniform dried reagent thickness; however, it would have been obvious to one with ordinary skill in the art at the time the invention was made to make the dried reagent layer uniform because this will increase the likelihood of uniform exposure of sample to reagent.

The van der Waal et al. reference does not mention a hand meter that can interface with the reagent test strip; however, adapting a reagent test strip so interface with and be read by a hand meter was known at the time of the invention as shown by the abstract and Figure 3 of the Nankai et al. reference and the abstract and Figure 1 of the North et al. reference. It would have been obvious to one with ordinary skill in the art at the time the invention was made to adapt the reagent test strip so that it can read by a hand meter as taught by the Nankai et al. reference and the North et al. reference because if the reagent test strip can be read by a hand meter it will be more convenient to use and on-site results of the measurements can be readily obtained.

Addressing claim 16, the reagent test strip being received by the meter is shown in Figure 2 of the Nankai et al. reference and implied by col. 2, ll. 39-42, which teaches that the sensor can be inserted into the meter.

Addressing Claim 21, the van der Wal et al. reference teaches a method of producing a reagent-coated substrate comprising

coating substrate with reagent in solution (col. 4, ll. 50-59), and

exposing the solution to radiant energy provided by at least one radiant energy heater (col. 4, ll. 50-59, especially col. 4, ll. 41-43).

The van der Waal et al. reference does not mention a substantially uniform dried reagent thickness; however, it would have been obvious to one with ordinary skill in the art at the time the invention was made to make the dried reagent layer uniform because this will increase the likelihood of uniform exposure of sample to reagent.

Applicant's detecting and relating steps are taught by Examples 1-3 (col. 4, ln. 33 – col. 5, ln. 11) which teaches making calcium ion concentration measurements.

The van der Waal et al. reference does not mention a hand meter that can interface with the reagent test strip; however, adapting a reagent test strip so interface with and be read by a hand meter was known at the time of the invention as shown by the abstract and Figure 3 of the Nankai et al. reference and the abstract and Figure 1 of the North et al. reference. It would have been obvious to one with ordinary skill in the art at the time the invention was made to adapt the reagent test strip so that it can read by a hand meter as taught by the Nankai et al. reference and the North et al. reference because if the reagent test strip can be read by a hand meter it will be more convenient to use and on-site results of the measurements can be readily obtained.

14. Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over van der Wal et al. (US 5,238,548) in view of Leader et al. (US 5,421,981) and Savage (US 5,284,570).

Addressing claim 17, the van der Wal et al. reference teaches a reagent-coated substrate for use in determining the concentration of an analyte in a physiological sample, comprising

a reagent test strip prepared (as required by claim 8) by

coating substrate with reagent in solution (col. 4, ll. 50-59), and

exposing the solution to radiant energy provided by at least one radiant energy heater (col. 4, ll. 50-59, especially col. 4, ll. 41-43).

The van der Wal et al. reference does not mention a substantially uniform dried reagent thickness; however, it would have been obvious to one with ordinary skill in the art at the time

the invention was made to make the dried reagent layer uniform because this will increase the likelihood of uniform exposure of sample to reagent.

The van der Wal et al. reference also does not mention providing a reagent test strip in a kit that also includes directions for use, a means for obtaining a physiological sample and an analyte standard.

The Leader et al. reference and the Savage et al. reference teach providing in a kit for a reagent test strip means for obtaining a physiological sample and an analyte standard (in the Leader et al. reference seethe abstract; Figure 1; col. 14, ll. 1-4; and col. 14, ll. 34-41. in the Savage et al. reference see the abstract and Figure 4). It would have been obvious to one with ordinary skill in the art at the time the invention was made to include in a kit for a reagent test strip means for obtaining a physiological sample and an analyte standard as taught by the Leader et al. reference and the Savage et al. reference in the van der Wal et al. reference because it is more convenient for the person who will use the reagent test strip to have the necessary components altogether in a kit so that the reagent test strip can be more quickly set up for use than if these components were separately stored.

As for directions for use, it would have been obvious to provide such directions so that the reagent test strip will be properly used.

15. Claims 7, 19, and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hanazato et al. (US 4,894,339).

Addressing claim 7, the Hanazato et al. reference teaches a method of producing a reagent-coated substrate comprising

coating substrate with reagent in solution (col. 2, ll. 37), and

exposing the solution to radiant energy provided by at least one radiant energy heater (col. 2, ll. 37-47).

The Hanazato et al. reference does not mention the intensity of the radiant energy; however, barring evidence to the contrary, such as unexpected results, choosing the intensity of the radiant energy, such as an intensity within the claimed range, is just a matter of optimizing the coating method. The intensity of the radiant energy used will be primarily limited by possible damage to the coating or substrate. For example, an excessive intensity of radiant energy can damage the reagent, such as an enzyme, directly or indirectly, by excessive heating.

Addressing claims 19 and 20, the Hanazato et al. reference teaches a method for determining the concentration of an analyte in a sample, the method comprising providing a reagent-coated substrate prepared (as required by claim 8) by

coating substrate with reagent in solution (col. 2, ll. 37), and

exposing the solution to radiant energy provided by at least one radiant energy heater (col. 2, ll. 37-47).

Note that Figures 3C and 5 show a substantially uniform thickness of dried reagent.

Applicant's detecting and relating steps is taught by Example 12 (col. 14, ll. 25-36) which teaches making glucose ion concentration measurements.

Although not specifically mentioned, it would have been obvious to one with ordinary skill in the art at the time the invention was made to make measurements on a biological sample because the Hanazato et al. reference teaches that the reagent test strip can be part of a biosensor and can be used for making glucose measurements (col. 3, ll. 30-45 and col. 1, ln. 54 – col. 2, ln. 10).

16. Claims 14-16 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hanazato et al. (US 4,894,339) in view of Nankai et al. (US 5,266,179) and North et al. (US 5,221,457).

Addressing claim 14, the Hanazato et al. reference teaches a method of producing a reagent-coated substrate comprising

coating substrate with reagent in solution (col. 2, ll. 37), and

exposing the solution to radiant energy provided by at least one radiant energy heater (col. 2, ll. 37-47).

Note that Figures 3C and 5 show a substantially uniform thickness of dried reagent.

The Hanazato et al. reference also does not mention whether the reagent test strip can be read by a hand meter; however, adapting a reagent test strip so that it can be read by a hand meter was known at the time of the invention as shown by the abstract and Figure 3 of the Nankai et al. reference and the abstract and Figure 1 of the North et al. reference. It would have been obvious to one with ordinary skill in the art at the time the invention was made to adapt the

reagent test strip so that it can read by a hand meter as taught by the Nankai et al. reference and the North et al. reference because if the reagent test strip can be read by a hand meter it will be more convenient to use and on-site results of the measurements can be readily obtained.

Addressing claim 15, the Hanazato et al. et al. reference teaches a system for determining the concentration of an analyte in a physiological sample comprising a reagent test strip prepared (as required by claim 8) by

coating substrate with reagent in solution (col. 2, ll. 37), and

exposing the solution to radiant energy provided by at least one radiant energy heater (col. 2, ll. 37-47).

Note that Figures 3C and 5 show a substantially uniform thickness of dried reagent.

The Hanazato et al. reference does not mention a hand meter that can interface with the reagent test strip; however, adapting a reagent test strip so interface with and be read by a hand meter was known at the time of the invention as shown by the abstract and Figure 3 of the Nankai et al. reference and the abstract and Figure 1 of the North et al. reference. It would have been obvious to one with ordinary skill in the art at the time the invention was made to adapt the reagent test strip so that it can read by a hand meter as taught by the Nankai et al. reference and the North et al. reference because if the reagent test strip can be read by a hand meter it will be more convenient to use and on-site results of the measurements can be readily obtained.

Addressing claim 16, the reagent test strip being received by the meter is shown in Figure 2 of the Nankai et al. reference and implied by col. 2, ll. 39-42, which teaches that the sensor can be inserted into the meter.

Addressing claim 21, the Hanazato et al. reference teaches a method for determining the concentration of an analyte in a sample, the method comprising providing a reagent-coated substrate prepared (as required by claim 8) by

coating substrate with reagent in solution (col. 2, ll. 37), and

exposing the solution to radiant energy provided by at least one radiant energy heater (col. 2, ll. 37-47).

Note that Figures 3C and 5 show a substantially uniform thickness of dried reagent.

Applicant's detecting and relating steps is taught by Example 12 (col. 14, ll. 25-36) which teaches making glucose ion concentration measurements.

The Hanazato et al. reference does not mention a hand meter that can interface with the reagent test strip; however, adapting a reagent test strip so interface with and be read by a hand meter was known at the time of the invention as shown by the abstract and Figure 3 of the Nankai et al. reference and the abstract and Figure 1 of the North et al. reference. It would have been obvious to one with ordinary skill in the art at the time the invention was made to adapt the reagent test strip so that it can read by a hand meter as taught by the Nankai et al. reference and the North et al. reference because if the reagent test strip can be read by a hand meter it will be more convenient to use and on-site results of the measurements can be readily obtained.

17. Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hanazato et al. (US 4,894,339) in view of Leader et al. (US 5,421,981) and Savage et al. (US 5,284,570).

Addressing claim 17, the van der Wal et al. reference teaches a reagent-coated substrate for use in determining the concentration of an analyte in a physiological sample, comprising

a reagent test strip prepared (as required by claim 8) by

coating substrate with reagent in solution (col. 2, ll. 37), and

exposing the solution to radiant energy provided by at least one radiant energy heater (col. 2, ll. 37-47).

Note that Figures 3C and 5 show a substantially uniform thickness of dried reagent.

The Hanazato et al. reference also does not mention providing a reagent test strip in a kit that also includes directions for use, a means for obtaining a physiological sample and an analyte standard.

The Leader et al. reference and the Savage et al. reference teach providing in a kit for a reagent test strip means for obtaining a physiological sample and an analyte standard (in the Leader et al. reference seethe abstract; Figure 1; col. 14, ll. 1-4; and col. 14, ll. 34-41. in the Savage et al. reference see the abstract and Figure 4). It would have been obvious to one with ordinary skill in the art at the time the invention was made to include in a kit for a reagent test strip means for obtaining a physiological sample and an analyte standard as taught by the Leader et al. reference and the Savage et al. reference in the Hanazato reference because it is more convenient for the person who will use the reagent test strip to have the necessary components altogether in a kit so that the reagent test strip can be more quickly set up for use than if these components were separately stored.

As for directions for use, it would have been obvious to provide such directions so that the reagent test strip will be properly used.

Allowable Subject Matter

18. Claim 2 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

19. Claims 3 and 6 would be allowable if rewritten to overcome the rejection under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

20. The following is a statement of reasons for the indication of allowable subject matter:

a) Claim 2 requires airflow sufficient only to break a vapor barrier of the solution is directed at the solution while exposed to the radiant energy. Although the Shieh et al. reference does teach using airflow, it does not teach using airflow in conjunction with radiant energy to dry the reagent solution. The Shieh et al. reference only discloses airflow and radiant energy as

alternative means for drying the reagent solution (col. 12, ll. 23-39). In the van der Wal et al. reference the reagent solution is in a nitrogen atmosphere while exposed to the radiant energy (col. 4, ll. 58-59 and col.5, ll. 9-10). The Hanazato et al. reference does not mention using airflow to dry the reagent solution. Although the reagent solution appears to be in an air atmosphere while exposed to eth radiant energy, the air is not being caused to flow so as to only break a vapor barrier of the solution;

b) Claim 3 requires the substrate to be provided in a roll and fed past the radiant energy source. Neither the Shieh et al. reference, the van der Wal et al. reference, nor the Hanazato et al. reference teach these limitations. Each of these references only teaches preparing an individual substrate. The Shieh et al. reference, for example, teaches dip coating a wire into solution and then drying.

The Wogoman et al. reference teaches feeding a substrate in a roll, coating it with solution, and then drying it with radiant energy (the abstract; Figure 4; and col. 11, ll. 40-45). However, in the Wogman et al. reference the coating prepared as just described is a membrane solution for a glucose permeable membrane. The reagent (glucose oxidase) in the Wogoman et al. reference is chemically attached to the working electrode before the membrane is coated onto the substrate. It would not have been obvious to substitute the membrane of the Shieh et al. reference for that of the Wogoman et al. reference because the Shieh et al. reference is directed to an ion sensor. It would not have been obvious to substitute the membrane of the Hanazato et al. reference or the membrane of the van der Wal et al. reference for that of the Wogoman et al.

reference because the Hanazato et al. reference or the membrane and the van der Wal et al. reference use ISFET's (Ion Sensitive Field Effect Transistors); and

c) Claim 6 appears to properly depend from allowable claim 3 (see the rejection of claim 6 under 35 U.S.C. 112, second paragraph, above).

21. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ALEX NOGUEROLA whose telephone number is (703) 305-5686. The examiner can normally be reached on M-F 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, NAM NGUYEN can be reached on (703) 308-3322. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.

Alex Noguerola
Alex Noguerola
9/28/2003
Primary Examiner
TC 1700